K093286

510(k) Summary

NOV 13 2009

PowerCross™ .018" OTW PTA Dilatation Catheter

510(k) Summary	This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR § 807.92.
Applicant	ev3 Inc.
Submitter	ev3 Inc. 3033 Campus Drive Plymouth, MN 55441 Tel: 763-398-7000 Fax: 763-591-3248
Contact Person	Sara Bakker Regulatory Affairs Specialist
Date Prepared	October 16, 2009
Device Trade Name	PowerCross™ .018" OTW PTA Dilatation Catheter
Device Common Name	PTA Dilatation Catheter
Classification Name	Catheter, Percutaneous (21 CFR 870.1250, Product Code DQY)
Classification Panel	Cardiovascular
Predicate Device	NanoCross™ .014" OTW PTA Dilatation Catheter (K090849) EverCross™ .035" OTW PTA Dilatation Catheter (K082579)
Intended use	The PowerCross .018" OTW PTA Dilatation Catheter is intended to dilate stenoses in the iliac, femoral, ilio-femoral, popliteal, infra-popliteal, and renal arteries, and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae. This device is also intended for stent post-dilatation.
Device Description	The PowerCross™ .018" OTW PTA Dilatation Catheter is an over the wire (OTW) 0.018" coaxial catheter with a distally mounted semi-compliant inflatable balloon and an atraumatic tapered tip. The distal portion of the catheter has a hydrophilic coating. The manifold includes a lumen marked "THRU". This is the central lumen of the catheter, which terminates at the distal tip. This lumen is used to pass the catheter over a guidewire with a maximum diameter of 0.018". The lumen marked "BALLOON" is the balloon inflation lumen, which is used to inflate and deflate the dilatation balloon with a mixture of contrast medium and saline solution. The balloon has two radiopaque markers for positioning the balloon relative to the stenosis. The radiopaque marker bands indicate the dilating or working section of the balloon. On the 150 and 200 mm devices, two additional marker bands denote the middle of the balloon body. The PowerCross .018" OTW PTA Dilatation Catheter is available in multiple balloon sizes. Nominal balloon diameter and length are printed on the strain relief.

Performance data	Bench testing was performed to support a determination of substantial equivalence. Results from this testing provide assurance that the proposed device has been designed and tested to assure conformance to the requirements for its intended use.
Summary of Substantial Equivalence	The PowerCross .018" OTW PTA Dilatation Catheter has the following similarities to the legally marketed NanoCross .014" and EverCross .035" OTW PTA Dilatation Catheters: • Same indicated use as EverCross (K082579), • Same operating principle, • Same device materials as NanoCross (K090849), • Same fundamental scientific technology, • Same packaging and sterilization processes.
Conclusion	Based on the intended use, technological characteristics, safety and performance testing, the PowerCross .018" OTW PTA Dilatation Catheter has been shown to be appropriate for its intended use and is considered to be substantially equivalent to the legally marketed NanoCross .014" OTW PTA Dilatation Catheter (K090849) and EverCross .035" OTW PTA Dilatation Catheter (K082854).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

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ev3 Inc.
c/o Ms. Sara Bakker
9600 54th Avenue North
Plymouth, MN 55442

Re: K093286
PowerCross 0.018" OTW PTA Dilatation Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: LIT, DQY
Dated: October 16, 2009
Received: October 20, 2009

Dear Ms. Bakker:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K093286

Device Name: PowerCross™ .018" OTW PTA Dilatation Catheter

Indications for Use:

The PowerCross .018" OTW PTA Dilatation Catheter is intended to dilate stenoses in the iliac, femoral, ilio-femoral, popliteal, infra-popliteal, and renal arteries, and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae. This device is also indicated for stent post-dilatation in the peripheral vasculature.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

...(ODE Sign-Off)
...ion of Cardiovascular Devices

...) Number K093286